

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

ABBOTT DIABETES CARE, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 05-590-GMS
	)	
DEXCOM, INC.,	)	
	)	
Defendant.	)	

**DECLARATION OF ANDREW K. BALO IN SUPPORT OF  
DEXCOM, INC.'S MOTION TO DISMISS THE  
COMPLAINT OF ABBOTT DIABETES CARE, INC.**

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Dated: August 31, 2005  
160976.1

1. I, Andrew K. Balo, have personal knowledge of the facts stated in this affidavit, and I could competently testify to them if called upon to do so.

2. I serve as DexCom, Inc.'s Vice President of Clinical and Regulatory Affairs and Quality Systems, overseeing all of DexCom's clinical trials, statistical analysis, regulatory submissions and quality assurance areas.

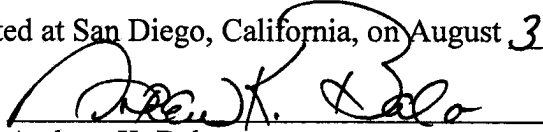
3. DexCom's continuous short-term glucose monitoring system ("STS") is the subject of a Pre-Market Approval application submitted to the FDA in March of 2005. The FDA has not yet approved DexCom's PMA application. To date, all of the STS systems made by DexCom have been for the purpose of obtaining FDA approval. Until the FDA approves the STS system, that is the only permitted use for the STS system. Since the STS system could be modified prior to FDA approval (whether by DexCom's choice or because of a rejection by the FDA), it would be pointless for DexCom to begin manufacture of the devices for commercial sale before the approval is clearly made evident from the FDA.

4. In 2005, DexCom has attended two diabetes-related conferences: the American Diabetes Association's ("ADA") "66th Scientific Sessions" held in San Diego, California during June of 2005, and the American Association of Diabetes Educators' ("AADE") August 2005 conference in Washington, D.C. DexCom attended those conferences for the purpose of exposing the devices to potential clinical collaborators, to support the current PMA and to support future regulatory filings in the United States and abroad. The conferences are attended by a large number of potential clinical investigators from the United States and abroad, and presents the most cost-effective method for a development-stage company, like DexCom, to contact potential clinical investigators. As the "sponsor" of the STS system in the FDA PMA process, DexCom is solely responsible for identifying qualified, interested physicians and enlisting them to participate in clinical trials. The data from those clinical trials is then used to support the safety and efficacy of the STS system to the FDA.

5. FDA regulations prohibit displaying an investigational device, or a device whose PMA application has yet to be approved, for commercial purposes. DexCom has abided by

those regulations with respect to the STS system. Indeed, during both the ADA conference and the AADE conference, DexCom's STS system was displayed (but never demonstrated) in tightly controlled environments and in sealed cases. No literature describing or promoting the product, no specifications or performance claims, and no samples of the STS system, were displayed or distributed at the scientific conferences. Only a few prototype product examples, similar to those that might be used in clinical trials, were displayed inside sealed cases. In fact, all displays were clearly labeled "Investigational Device: Limited by U.S. Federal Law to Investigational Use. Not Available for Sale." Moreover, the representatives from DexCom who were present at the DexCom booth were members of my department (the Clinical and Regulatory Affairs and Quality Systems department) and research and development. DexCom has no sales staff or employees, and therefore there were no sales staff at the booth or interacting with the conference attendees.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed at San Diego, California, on August 31, 2005.



Andrew K. Balo

**CERTIFICATE OF SERVICE**

I hereby certify that on the 31<sup>st</sup> day of August, 2005, the attached **DECLARATION OF ANDREW K. BALO IN SUPPORT OF DEXCOM, INC.'S MOTION TO DISMISS THE COMPLAINT OF ABBOTT DIABETES CARE, INC.** was served upon the below-named counsel of record at the address and in the manner indicated:

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HAND DELIVERY

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VIA FEDERAL EXPRESS

*/s/ Steven J. Balick*

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Steven J. Balick